



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 2, 2016

Encore Medical, L.P.
Ms. Teffany Hutto
Manager, Regulatory Affairs
9800 Metric Boulevard
Austin, Texas 78758-5445

Re: K103208

Trade/Device Name: Reverse® Shoulder Prosthesis Monoblock
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS
Dated: October 29, 2010
Received: November 1, 2010

Dear Ms. Hutto

This letter corrects our substantially equivalent letter of January 31, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K103208

Device Name: Reverse Shoulder Prosthesis Monoblock

Indications for Use:

Reverse® Shoulder Prosthesis Monoblock
Indications for Use

The Reverse Shoulder Prosthesis Monoblock is indicated for patients with a functional deltoid muscle with a grossly deficient rotator cuff shoulder joint with severe arthropathy or a previously failed joint replacement with a grossly deficient rotator cuff shoulder joint:

- In cases of fracture of glenohumeral joint from trauma or pathologic conditions of the shoulder, including humeral head fracture or displaced 3-or 4-part fractures of proximal humerus.
- In cases of bone defect in proximal humerus.

The patient's joint must be anatomically and structurally suited to receive the selected implant(s).

The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral stem is intended for cemented use only.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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Summary of Safety and Effectiveness JAN 3 1 2011

Date: January 26, 2011

Contact Person:

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Product	S10(k) Number, Classification	Product Code
Reverse® Shoulder Prosthesis Monoblock	K103208, Class II	KWS

Product Code	Regulation and Classification Name
KWS	Shoulder joint metal/polymer semi-constrained prosthesis per 21 CFR 888.3660

Description:

The Reverse Shoulder Prosthesis (RSP) is indicated for salvage procedures for irreparable rotator cuff, failed hemi or total shoulder arthroplasty with irreparable rotator cuff, and for fracture in which the tuberosity and rotator cuff are irreparable. The RSP is designed so that the "ball" of the articulation fits into the glenoid baseplate, and the "cup" of the articulation fits into a metal cup attached to the humeral stem. The components included in this system are a glenoid head, a humeral socket, a humeral stem, a glenoid baseplate, and baseplate screws.

The Monoblock design consists of:

- a non-modular stem designed by joining the humeral socket with the humeral stem (sizes 6, 7, 8, 10 and 12);
- humeral inserts in size 44 semi-constrained UHMWPe and +4 offset inserts in sizes 32, 36, 40 and 44 (standard and semi-constrained UHMWPe). Currently cleared sizes of inserts (32, 36, 40, and 44 in standard poly and size 32, 36, and 40 semi-constrained UHMWPe) are also compatible with the monoblock design.
- glenoid components will be the same as currently cleared under K100741, K092873, K051075, and K041066

Indications for Use:

The Reverse Shoulder Prosthesis Monoblock is indicated for patients with a functional deltoid muscle with a grossly deficient rotator cuff shoulder joint with severe arthropathy or a previously failed joint replacement with a grossly deficient rotator cuff shoulder joint:

- In cases of fracture of glenohumeral joint from trauma or pathologic conditions of the shoulder, including humeral head fracture or displaced 3-or 4-part fractures of proximal humerus.
- In cases of bone defect in proximal humerus.

The patient's joint must be anatomically and structurally suited to receive the selected implant(s).

The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral stem is intended for cemented use only.

Predicate Device:

- K082120 – Tornier Aequalis®-Reversed Fracture prosthesis

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Comparable Features to Predicate Device(s):

- Single cup diameter accepts multiple articular diameters
- Multiple stem diaphysis diameters
- Titanium alloy construction
- Coated Metaphysis
- Single piece stem/metaphysis construction
- Anatomic positioning of tuberosities
- Bone graft attachment
- Medial cerclage suture hole

Non-Clinical Testing: After completing review of prior non-clinical testing conducted for this system and submitted under K100741, K092873, K051075, and K041066, it was concluded that additional testing was not necessary to support equivalence.

Clinical Testing: None provided.